Scancell

US IND for SCIB1 gives Phase II study the green light

3 February 2020

- Scancell has announced that the FDA has cleared the SCIB1 IND (Investigational New Drug) application. This means that both the UK and US arms of the Phase II trial, evaluating the SCIB1 vaccine in combination with the checkpoint inhibitor pembrolizumab (Keytruda) in metastatic melanoma, can now start.
- The US element of the trial had been delayed due to the FDA having a number of questions regarding Ichor Medical Systems' TriGrid v2.0 electroporation delivery device. This is a newer commercial version of the device that was employed in earlier clinical work. The resolution allows Scancell to initiate US site activities and patient enrolment, alongside UK clinical site expansion.
- The study will examine the tumour response rate, progression-free survival and overall survival in 25 patients with advanced melanoma. The aim is to explore if combination with a checkpoint inhibitor will improve treatment response with acceptable toxicities.
- Scancell's second ImmunoBody, SCIB2, uses a novel lipid nanoparticle formulation. The forthcoming CRUK-funded Phase I/II study will employ this via a standard injection, rather than using electroporation. Preclinical studies suggest the nanoparticle formulation is at least comparable to, and could be better than, using electroporation.

Price	6.55p
Market Cap	£30.5m
Primary exchange	AIM
Sector	Healthcare
Company Code	SCLP.L
Corporate client	Yes

Company description:

Scancell is a clinical-stage immuno-oncology specialist that has three technology platforms. Two flexible therapeutic vaccine platforms are progressing through development. ImmunoBody and Moditope induce high avidity cytotoxic CD8 and CD4 responses, respectively, with the potential to treat various cancers.

Trinity Delta view: ImmunoBody is the most clinically advanced of Scancell's three technology platforms. ImmunoBody vaccines have an elegant design that targets dendritic cells. They achieve efficient direct and cross-presentation of specific epitopes (peptide sequences from proteins), and a consistently strong anti-tumour immune response. Promising activity was seen in a SCIB1 monotherapy Phase I/II melanoma study, but the real potential, in our view, is in combination with checkpoint inhibitors. The FDA's green light for the US arm of the Phase II study is a welcome step forward and allows management to re-build momentum.

We maintain our valuation of £82.0m, equivalent to 17.2p a share. There are various likely catalysts over the coming year; including further AvidiMab collaborations, the SCIB1 UK trial being underway, and news flow on the timings of the first SCIB2 and Moditope clinical studies.

Analysts

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